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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/466,308 06/06/95 KAUFMAN

R 118-6415/PCT

EXAMINER

MERTZ, P

18N2/1109

ART UNIT

PAPER NUMBER

ROBERT S HONOR  
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1812

DATE MAILED:

11/09/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

*for restriction purposes only*

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ \_\_\_\_\_

Part II SUMMARY OF ACTION

1. ☒ Claims 1-18 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2. ☐ Claims \_\_\_\_\_ have been cancelled.

3. ☐ Claims \_\_\_\_\_ are allowed.

4. ☐ Claims \_\_\_\_\_ are rejected.

5. ☐ Claims \_\_\_\_\_ are objected to.

6. ☒ Claims 1-18 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1812

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

5       Group I. Claims 1-8, 14, 16 and 18, drawn to a recombinant CSF protein or CSF protein, and pharmaceutical compositions thereto, classified in Class 424 and 530, subclass 85.1 and 351, respectively.

      Group II. Claims 9-11, and 13, drawn to a method of producing a CSF protein, a cDNA or an expression vector, and host cell, classified in Class 435, subclass 69.5.

10       Group III. Claim 12, drawn to a method for purifying CSF protein, classified in Class 530, subclass 412.

      Group IV. Claims 15, and 17, drawn to a method of treatment with CSF, classified in Class 424 and 514, subclass 85.1 and 2, respectively.

15       The inventions are distinct, each from the other because of the following reasons:

20       Inventions II or III and invention I are related as alternative processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the CSF protein can be prepared

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by either of the processes of Groups II and III as shown above. Alternatively, the protein can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

5

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product  
10 or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the CSF protein can be used to treat various disorders as shown by the different methods of claims 15 and 17. Alternatively, the protein can be used to make antibodies or it  
15 could be used in diagnostic procedures.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for inventive groups that are directed to **different** methods, restriction is deemed to be  
20 proper, because these products appear to constitute patentably distinct inventions for the following reasons: the methods of Groups II-IV have different goals, method steps, starting materials, and are not required one for the other. In addition, the search for one of the methods would not be expected to reveal

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all references relevant to the other, and therefore the search and examination would be unduly burdensome.

5       Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and as shown by their different classification, restriction for examination purposes as indicated is proper.

10       A telephone call was made to Melvyn Kassenoff on 3 November 1995 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicants requested a written restriction.

15       Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

20       Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must

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be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:00PM (Eastern time).

10 If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Garnette D. Draper, can be reached on (703) 308-4232.

15 Papers related to this application may be submitted to Group 1800 in Crystal Mall 1 by facsimile transmission, in conformity with the notice published in the official Gazette, 1096 OG 30 (November 15, 1989). The FAX phone number for Art Unit 1812 is (703) 308-0294.

20 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

25 Prema Mertz, Ph.D.  
Examiner  
November 6, 1995

*Stephen Walsh*  
**STEPHEN G. WALSH**  
**PRIMARY EXAMINER**  
**GROUP 1800**